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CONSULTATION . RESEARCH . INFORMATION SPECIALISTS

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Mr. Ed Carmines Philip Morris PO Box 26583 Richmond, VA 23261

Lear Mr. Carmines:

I appreciate the opportunity to speak with you by telephone today. To explain in detail more about the services we can offer and provide some specifics of the approach I use in successful LIMS implementations as a part of my consulting practice. I offer the following outline of some of the methodologies I use. It is important to remember that I function as an unbiased LIMS consultant. I offer no system of my own. I have no vested interest in recommending one vendor's system over another, and I do not write custom software for consulting clients. I work on my client's behalf only. I have no special relationship with any particular vendor and therefore I am free to recommend only what is truly in the best interest of my client. In one case, the paper based system the client currently used was far better suited to their particular and unique need that any LIMS system then available would supply. For them, the ideal solution was partial instrument automation.

Basically, we conduct a laboratory needs assessment by interviewing laboratory personnel, reviewing and evaluate workflow, reviewing analytical report formats, examining laboratory instrumentation, and investigating alternatives to improve productivity. Working with the LIMS Task Force or LIMS Team, we review my findings and conduct, if necessary, JAD (Joint Application Design) meeting(s) to assess the users wish lists and design the "ideal" LIMS for your laboratory. One this is done the Request for Proposal (RFP) is written.

I must mention that writing the request for proposal can be a difficult and sometimes a daunting task. I usually write the RFP for my clients by following the procedures given below. After completely understanding my client's needs and putting the requirements into a formal proposal, I generally send the RFP to no more than five or six vendors, based on my knowledge of their system capabilities and the means by which I believe they can address the client's needs. Price can sometimes be a limiting factor but in many cases it isn't.

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Together with the LIMS Team, we decide on the basis upon which the RFP responses will be scored. The responses to the RFP are evaluated on this numerical basis and then, based on their respective scores, two vendors are requested to do a full blown exhibit of their system paying particular attention to those areas our task force has identified. This same process is repeated for the demonstrations so that the clear winner emerges.

If the people in the laboratory are not familiar with a LIMS and LIMS functionality, I usually present an overview of a LIMS for them even before the interview process so that they will know the direction we are headed and at least some of the reasons for the questions I ask. Informed end users are one of the greatest keys to success and I ensure that everyone, including top management, is involved in the selection process.

No one system is best in every laboratory environment. There are many considerations, some of them guite abstract, that enter into the LIMS decision.

I am pleased to provide the following outline of my role and the procedures I follow:

Basically, my role in the successful implementation of a LIMS into a company involves four separate, but closely integrated procedures. They are:

- 1. Identify the information needs of a laboratory, in conjunction with management and users.
- Assist in the unbiased selection of the best hardware and software for the operations anticipated.
- 3. Plan for the integration of the proposed system.
- 4. Assist in getting the new system installed and running.

I assist in the selection process and ensure the integrity of the vendors' information. My role may be as large or as small as the client desires.

I found in my experience that the following steps work best in providing a firm foundation upon which to base the written RFP (Request for Proposal):

A. First, I receive an introduction to the sample and information flow in the laboratory.

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- B. After becoming at least superficially familiar with the laboratory data flow, a rather extensive interview process takes place. This is a crucial step. I interview many of the end users one on one, based on the role each individual plays in the information flow process. Each interview ranges from approximately fifteen minutes to one hour in length.
- C. After these interviews are completed and the results analyzed, a LIMS Task Force may be formed and JAD (Joint Application Design) meetings are scheduled. The task force is chosen by me and senior management personnel. These discussion/design meetings with the LIMS Task Force are held in order to ascertain their priorities and "wish lists". In addition, many unique features of your laboratory operation are uncovered during this process. These meetings basically determine the way your LIMS system will function.
- D. All current forms such as sample log in forms, results entry forms, reports, summaries, charge backs, priority lists, cost analyses, etc., are examined and analyzed. We determine those areas in need of change and those that may remain as they are.
- E. Based on the review, analysis, and evaluation of all data acquired both in the interview, appraisal process, JAD meetings, and data analysis, a recommendation is made as to the generic configuration of LIMS necessary. This is generally presented in the form of a RFP (Request for Proposal) suitable for submission to the vendors.
- F. A listing of suitable LIMS vendors is selected to send the RFP for response.
- G. The responses are evaluated in conjunction with the LIMS Task Force and two or three appropriate vendors are selected for an on-site demonstration of their configured system. If a custom house is selected, an on-site presentation is arranged, although a custom LIMS is rarely a good solution.

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H. A suitable LIMS vendor is selected for final negotiation on price, delivery, and tailoring.

Obviously there are many intangibles and smaller steps involved in each of the above procedures. It is not possible to define each of them in advance because many are determined only during my on-site visit.

These steps may be completed with as few as two or three on-site visits depending on how extensive a role I play. A significant portion of my work can be done in my office and results communicated by facsimile. Telephone contact or the internet can also be used to communicate.

I would look forward to working with you and the additional staff people at your facility to ensure a successful LIMS implementation. The cost, not only in money spent for the wrong LIMS, but in time wasted, lost opportunities, wasted training costs, and other various factors, in choosing the wrong LIMS system can be enormous. The potential economic benefits and productivity increases far outweigh the trauma of implementation as long as the correct LIMS is chosen carefully. My role is to make the successful transition as easy and cost effective as possible.

If questions remain, please don't hesitate to contact me.

Very truly yours,

Martin Goffman, Ph.D.

Principal